

I. Introduction

In June 2003, the legislature created the Prescription Drug Program (PDP) in Senate Bill 6088 (SB 6088) (Ch. 29 Laws of 2003 1st Special Session) to control state prescription drug costs without reducing the quality of care, to develop programs that provide affordable prescription drugs to those in need, and to increase public awareness regarding their safe and cost-effective use.

The PDP is a joint effort by the Health Care Authority (HCA), the Department of Social & Health Services (DSHS), and the Department of Labor & Industries (L&I) (hereinafter “the agencies”). It consists of five main components: a Medicaid Prescription Drug Assistance Program, a Senior Prescription Drug Discount Card, a “Pharmacy Connections” program, a Senior Drug Education Program, and an Evidence-Based Preferred Drug List (PDL)/Therapeutic Interchange Program (TIP).

The HCA has developed a comprehensive website (www.rx.wa.gov) where consumers, providers, and other interested parties can get comprehensive information about all of the state’s prescription drug programs, as well as links to resources nationwide.

This progress report on the agencies’ implementation of SB 6088 is submitted under the requirements of SB 6088 section 11.¹

II. Executive Summary

SB 6088 section 2: Medicaid Prescription Drug Assistance Program (MPDA)²

DSHS did not apply to the Center for Medicare and Medicaid Services (CMS) to obtain a Pharmacy Plus waiver based on the federal government’s enactment of the “Medicare Prescription Drug, Improvements and Modernization Act of 2003” (MMA). Beginning January 1, 2006, Medicare will begin offering prescription drug benefits (Part D) to Medicare beneficiaries. MMA also will provide low-income subsidies for beneficiaries with incomes up to 150% of the federal income guideline. Under MMA, Medicaid funding can no longer be used to finance prescription drug coverage for Medicare beneficiaries that would otherwise be covered under Part D.

SB 6088 sections 3 and 4: the Senior Prescription Drug Discount Card³

The Senior Prescription Drug Discount Card became available June 1, 2004. It is a mail order discount drug program for Washington residents over 50 years old who have no other prescription drug coverage and who earn less than 300% of the federal income guideline (approximately \$2,328 per month for an individual). The discount card costs

¹ RCW 41.05.530

² RCW 74.09.650

³ RCW 41.05.500, 510; RCW 43.131.403

\$10 per year and gives members a 15% to 25% discount on their prescription drugs. As of December 2004 approximately 25 residents have signed up for the discount card.

SB 6088 section 7: the Pharmacy Connections Program⁴

The Pharmacy Connections program (1-888-435-3377) was established in December 2003, to provide toll-free telephone assistance for Washington residents to get information about manufacturer-sponsored prescription drug assistance programs and to assist them with applying for these programs. The program also serves as a one-stop “clearinghouse” to provide information on other prescription drug resources such as the Medicare discount cards and the Washington Senior Prescription Drug Discount Card. Since implementation, the program has provided assistance to over 15,000 Washington residents.

SB 6088 section 8: the Senior Drug Education Program⁵

DSHS Aging & Disability Services Administration (ADSA) implemented the Senior Drug Education Program in November 2003. The program is designed to inform and train persons 65 and older in the safe and appropriate use of prescription and nonprescription medications. ADSA has provided grants to 11 Area Agencies on Aging to establish local programs. Programs range from distributing educational materials at health fairs, to individual classes that allow for one-on-one assistance to address specific medication regimens and their effects on each individual’s health and lifestyle.

Over 7,100 seniors have received training or information as of November 2004, and future training will incorporate information about the Medicare prescription drug benefit and other options available.

SB 6088 section 9: the Evidence-Based Preferred Drug List⁶

The Evidence-Based Preferred Drug List is a coordinated effort by HCA’s Uniform Medical Plan (UMP), DSHS’s Medical Assistance Administration (MAA) fee for service program, and L&I’s Workers’ Compensation Program to develop a statewide evidence-based PDL to encourage the use of less expensive, equally safe and effective drugs in state programs.

In January 2004, the agencies implemented a single PDL used by each of the agencies. As of January 1, 2005 the PDL consists of 12 drug classes. The agencies plan to add an additional 8 drug classes during 2005, and another 4 during 2006. The PDL will consist of 24 drug classes by January 2007.

The agencies select drugs for inclusion on the PDL based on the recommendations of the Washington State Pharmacy & Therapeutics Committee (P&T Committee). The P&T

⁴ RCW 41.05.520

⁵ RCW 74.09.660

⁶ RCW 70.14.050

Committee was established on July 15, 2003 and meets at least quarterly to consider reports on the evidence of drug safety and efficacy produced by the Evidence-Based Practice Center at Oregon Health & Sciences University.

The P&T Committee makes recommendations to the agencies as to which drugs within a therapeutic class it believes needs to be included on the PDL and which are similar in safety and efficacy. The agencies then select a preferred drug, or drugs, from those drugs based on an analysis of net cost to the state.

To encourage the use of preferred drugs, SB 6088 sections 5 and 6⁷ created a process by which practitioners can “endorse” the PDL. An “endorsing practitioner” is one who has reviewed the PDL and has notified the HCA that pharmacists can automatically “interchange” the preferred drug for any non-preferred drug prescribed unless the endorsing practitioner indicates, “dispense as written,” or it is for a “refill” of certain drugs specified in the statute. In these situations a pharmacist will dispense the non-preferred drug as prescribed. The agencies implemented the practitioner endorsement and therapeutic interchange program (TIP) the week of May 1, 2004.

III. Progress Report on Implementation of SB 6088

SB 6088 section 2: Medicaid Prescription Drug Assistance Program (MPDA)⁸

Legislative Summary:

- Subject to specific appropriations and conditions, MAA shall design a Medicaid prescription drug assistance program that shall not be an entitlement program.
- MAA shall request federal waivers necessary to implement the program and may charge enrollment fees, premiums, or point-of-service cost-sharing. The benefit design shall be cost-effective and may differ from the medical assistance program benefit design. MAA may offer more than one benefit design and may include a deductible benefit to provide coverage when enrollees incur higher prescription drug costs.
- Eligibility is limited to persons who: are eligible for Medicare or age 65 or older; whose family income does not exceed 200% of the FPL; lack prescription drug insurance coverage; and are not otherwise eligible under Title XIX.
- Enrollment may be limited to prevent over expenditure or to comply with federal waiver budget neutrality requirements.

⁷ RCW 69.41.150, .190

⁸ RCW 74.09.650

- MAA shall recommend financing options to the legislature by November 15, 2003, including exploring opportunities to maximize federal funding. MAA may not reduce existing programs to comply with federal waiver requirements nor use premiums paid by non-program enrollees to finance the program.
- The program terminates within 12 months after implementation of a prescription drug benefit under Title XVIII.

Implementation Status: DSHS did not apply to CMS to obtain a Pharmacy Plus waiver based on the federal government's enactment of the "Medicare Prescription Drug, Improvements and Modernization Act of 2003" (MMA). Beginning January 1, 2006, Medicare will begin offering prescription drug benefits (Part D) to Medicare beneficiaries. MMA also will provide low-income subsidies for beneficiaries with incomes up to 150% of federal income guideline. Under MMA, Medicaid funding can no longer be used to finance prescription drug coverage for Medicare beneficiaries that would otherwise be covered under Part D.

In December 2003, DSHS submitted a letter and status report to Governor Locke and the chairs and vice-chairs of the health policy and appropriation's committees recommending that Washington not proceed with seeking a Pharmacy Plus waiver because it would only provide coverage for about 18 months before the new Medicare benefit became available (**See Appendix I. – DSHS letter to Legislature regarding Medicaid Waiver Status**) DSHS indicated that it would not be able to meet 5-year waiver budget neutrality requirements because most persons that might seek Pharmacy Plus coverage would be able to get subsidized covered under Medicare Part D.

With potential enactment of Part D, CMS informally told the states that it would no longer accept Pharmacy Plus waiver applications because of the impending enactment of Medicare drug coverage. At that time, CMS had granted waivers to only 4 of 16 states prior to the announcement of its moratorium on further applications, five other states had either withdrawn or rejected applications and the other applicants were on hold until Congress completed its deliberations on Medicare prescription drug coverage. DSHS was not appropriated funding to finance a Pharmacy Plus waiver and was advised by legislators not to take further action until after Congressional action on prescription drug coverage.

Senate Bill 6088 sections 3, 4, 11, and 12: the Senior Prescription Drug Discount Program⁹

Legislative Summary:

- The HCA shall negotiate price discounts with prescription drug manufacturers for any Washington resident whose family income does not exceed 300% of the FPL; does not have prescription drug insurance coverage; and is 50 years or older; or

⁹ RCW 41.05.500, 510; RCW 43.131.403

between 19 and 49 and eligible for federal old age, survivors, and /or disability insurance benefits.

- An individual's attestation is sufficient to satisfy the income eligibility requirement. However, any person who willfully makes a false statement to qualify for the discounts is guilty of a misdemeanor.
- HCA shall charge program participants an annual enrollment fee to offset program administration costs. All such fees are to be deposited into the consolidated prescription drug purchasing account.
- Pharmaceutical manufacturer rebates and discounts for individuals shall not be provided at the expense of retail pharmacies. This does not prohibit state agency discounted reimbursements for pharmacy services or ingredients.
- The program terminates as of June 30, 2010 and the section is repealed as of June 30, 2011.

Implementation Status: The Senior Prescription Drug Discount Card became available June 1, 2004. The discount card costs \$10 per year and gives members a 15% to 25% discount on their prescription drugs.

The Senior Prescription Drug Discount Card is a mail order only program that is open to Washington residents covered by SB 6088 section 3 (residents over 50 or disabled who have no other prescription drug coverage, and who earn less than 300% of the federal poverty level) but that is specifically targeted at those who aren't eligible for the new Medicare discount card. The program is administered by Express Scripts, Inc. (ESI) under the HCA's Uniform Medical Plan (UMP) pharmacy benefits management contract. Administration costs for the discount card are supported by the \$10 annual enrollment fee. ESI collects the fee, provides enrollment and renewal materials, determines eligibility, and provides customer support.

As of December 2004 enrollment in the discount program was approximately 25 members. The limited nature of the program is the result of several factors: (1) the availability of the Medicare drug discount card, (2) HCA's inability to negotiate discounts that did not come at the expense of retail pharmacies (not allowed by SB 6088), (3) the existence of many new discount programs offered by drug manufacturers, and (4) the fact that it is a mail order only program (most suitable for long term prescription drug needs).

- Background on efforts to obtain individual discounts as envisioned by SB 6088.

The UMP negotiates discounts from pharmaceutical manufacturers through its pharmacy benefits manager, ESI. Manufacturers were not inclined to extend these discounts to non-UMP members because without the underlying UMP benefit structure (3-tier co-

insurance), there is no incentive for purchasers to shift to a particular manufacturer's products, justifying a discount.

The HCA also explored the possibility of obtaining manufacturer discounts by using the Washington State Preferred Drug List to create incentives to shift market share to particular manufacturers' products. However, this program was not yet fully operational at the time of our negotiations and manufacturers wanted to see how the program actually worked before committing to any discounts based on it. Finally, manufacturers were focused on implementing the new Medicare prescription drug discount cards that became available June 1, 2004.

As a result the HCA met with the Chairs of the Senate Health and Long Term Care and House Health Care committees, and stakeholders to reach a compromise to provide a mail order only Senior Prescription Drug Discount Card to provide discounts to Washington residents covered by SB 6088 section 3, specifically targeting those who are not eligible for the Medicare discount card program.

Senate Bill 6088 section 7: the Pharmacy Connection Program¹⁰

Legislative Summary:

- HCA shall establish a program to provide health care providers and the public, access to information about free or discounted medications from manufacturer-sponsored prescription drug assistance programs. The program specifically targets senior citizens, but is available to anyone. The program shall include a toll-free telephone number, available during regular business hours.
- Program staff help people gain access to these programs by:
 - Determining whether an assistance program is offered for a needed drug.
 - Evaluating the likelihood of a person obtaining drugs from an assistance program.
 - Assisting persons with the application and enrollment in an assistance program.
 - Coordinating with prescribers on communications on behalf of a person seeking access to an assistance program.
 - Working with manufacturers to simplify access to drug assistance programs, and to develop a single application form and uniform enrollment process.
- HCA may apply for and accept grants or gifts and may enter into interagency agreements or contracts with other state agencies to implement this program.

¹⁰ RCW 41.05.520

- HCA shall notify pharmaceutical companies doing business in Washington of the program and the companies shall notify HCA of all relevant information regarding pharmaceutical assistance programs operated by the company.

Implementation Status: The Pharmacy Connections program (1-888-435-3377) was established in December 2003, to provide toll-free telephone assistance for Washington residents to get information about manufacturer-sponsored prescription drug assistance programs and to assist them with applying for these programs. The program also serves as a one-stop “clearinghouse” to provide information on other prescription drug resources such as the Medicare discount cards and the Washington Senior Prescription Drug Discount card.

The Pharmacy Connections program is administered through an interagency agreement between the HCA and DSHS, Aging & Disabilities Services Administration (ADSA). It is a coordinated effort involving 11 Area Agencies on Aging (AAAs); the Office of the Insurance Commissioner’s Statewide Health Insurance Benefits Advisors (SHIBA), Senior Services of King County, and the Pharmaceutical Research and Manufacturer’s Association (PhRMA).

The program also makes available a database of discount programs called “BenefitsCheckUp,” which is a project of the National Council on Aging. Over 78 agencies in Washington State now use the database, and more than 300 agency staff and volunteers have been trained to use it as part of the Pharmacy Connections program. Since program implementation, AAA staff has provided referral information on drug manufacturer sponsored patient assistance programs and drug discount cards to over 15,000 individuals statewide. In addition to those contacts, they have also assisted over 11,000 individuals needing more help to complete applications. Included in the 11,000 are more than 5,300 BenefitsCheckUp screenings. SHIBA is also a partner in Pharmacy Connections, fielding more than 15,500 calls, over 11,000 web hits and making 627 public presentations. They also distributed over 70,000 pamphlets and flyers on related topics. (See Appendix II. – Senior Drug Education Program/Pharmacy Connections Data)

The number of contacts is expected to rise dramatically over the next six to nine months based on the confusion surrounding implementation of the new Medicare prescription drug benefit in 2006. All manufacturers offering discounts or free drug programs in Washington participate in Pharmacy Connections.

Senate Bill 6088 section 8: the Senior Drug Education Program¹¹

Legislative Summary:

- Each of the state's AAAs shall implement a program intended to inform and train persons age 65 and over in the safe and appropriate use of prescription and

¹¹ RCW 74.09.660

nonprescription medications. DSHS shall award development grants of up to \$25,000 to each agency upon a showing that:

- The agency has the ability to administer a program;
- The agency can bring resources to the program in addition to those funded by the grant; and
- The program will be collaborative between the agency and health care programs and providers in the area served.

Implementation Status: DSHS Aging & Disability Services Administration (ADSA) implemented the Senior Drug Education Program in November 2003. The program is designed to inform and train persons 65 and older in the safe and appropriate use of prescription and nonprescription medications. ADSA has provided grants to 11 Area Agencies on Aging to establish local programs. Programs range from classes of 2-15 individuals to allow for one-on-one assistance to address specific medication regimens and their effects on each individual's health and lifestyle, to distribution of educational materials at health fairs. ADSA has developed the infrastructure necessary to make this program available throughout the state.

The additional funding allowed the AAA's to plan programs unique to their service area and population. Strategies included:

- Recruiting volunteer pharmacy professionals from the community to work one-on-one with seniors who would bring their medications to a "brown bag event."
- Training AAA staff to present appropriate materials at Senior Centers, senior housing, and other target locations.
- Staffing booths and disseminating materials (including Smart Cards for recording Rx info) at Health Fairs and other senior events.
- Developing and collecting educational materials through various resources.
- Training medical professionals to be more aware of geriatric standards for prescribing medications.
- Public Service Announcement media publicity of local phone number to call for information.

As of November 2004, more than 7,100 seniors have been trained or received information at 275 events utilizing 222 volunteers and staff. Future training will incorporate information about the Medicare prescription drug benefit and other options available. (See **Appendix II. – Senior Drug Education Program/Pharmacy Connections Data**)

Senate Bill 6088 sections 5, 6, and 9: Evidence-Based Prescription Drug Program¹²

Legislative Summary:

Agencies administering state purchased health care programs shall cooperatively take actions to control costs without reducing the quality of care when purchasing drugs, including the development of the following:

- A “**Preferred Drug List (PDL)**” to limit the price paid for drugs through negotiated pharmaceutical manufacturer discounts.
- A “**Practitioner Endorsement**” process along with administrative rules necessary to govern the use of any list developed as part of the program.
- A “**Pharmacy and Therapeutics (P&T) Committee**” to evaluate the effectiveness of prescription drugs in the development of the PDL.
- A “**Therapeutic Interchange Program**” to allow pharmacists filling a prescription for a state purchased health care program to substitute, where identified, a preferred drug for any nonpreferred drug in a given therapeutic class,
 - unless the endorsing practitioner has indicated the prescription be “**Dispensed as Written (DAW)**”
 - or the prescription is for a “**refill**” of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug.
- The pharmacist shall notify the prescribing practitioner of the specific drug and dose dispensed.
- A pharmacist who makes a therapeutic substitution assumes no greater liability for substituting the preferred drug than would be incurred in filling a prescription for the preferred drug when prescribed by name.

Implementation Status:

Preferred Drug List (See Appendix III. – Prescription Drug Program Background Documents and Data)

On February 12, 2003, the HCA adopted administrative rules creating a single statewide PDL and governing its use.¹³ In January 2004, the agencies implemented the PDL. As of January 1, 2005 the PDL consists of 12 drug classes. The agencies plan to add an

¹² RCW 70.14.050; RCW 69.41.150, 190

¹³ WAC 182-50-005 (7)

additional 8 drug classes during 2005, and another 4 during 2006. The PDL will consist of 24 drug classes of drugs by January 2007.

The current 12 drug classes and their uses include:

1. ACE Inhibitors (heart disease/hypertension)
2. Beta Blockers (heart disease/hypertension)
3. Calcium Channel Blockers (heart disease/hypertension)
4. Estrogens (hormone replacement therapy)
5. Long Acting Opioids (chronic non-cancer pain)
6. Nonsteroidal Anti-inflammatory Drugs & COX II Inhibitors (acute/chronic pain or inflammation)
7. Oral Hypoglycemics (diabetes)
8. Proton Pump Inhibitors (gastric reflux, gastric & duodenal ulcers)
9. Skeletal Muscle Relaxers (muscle spasms)
10. Statins (cholesterol reduction)
11. Triptans (migraine)
12. Urinary Incontinence Drugs (urinary incontinence)

The next 12 drug classes scheduled for review by the P&T Committee include:

1. 2nd Generation Antidepressants (depression and or psychiatric indications)
2. Non-sedating Antihistamines (allergies)
3. Angiotensin II Receptor Antagonists (heart disease or hypertension)
4. Atypical Antipsychotic drugs (schizophrenia)
5. Inhaled Corticosteroids (asthma)
6. Drugs for the treatment of Attention Deficit/Hyperactive Disorder
7. Drugs for the treatment of Alzheimer Disease
8. Anti-platelet drugs (cardiovascular disease/stroke)
9. TZD (a class of oral medications to treat diabetes mellitus)
10. 5HT3 Antagonists (drugs for the treatment of severe nausea and vomiting)
11. Anti Tissue Necrosis Factor (treatment of diseases such as rheumatoid arthritis)
12. Sedative Hypnotics (sleep medication)

Endorsing Practitioner/Therapeutic Interchange Program (TIP)

Endorsing Practitioners: To encourage the use of preferred drugs, TIP allows practitioners to review and “endorse” the PDL and notify the HCA that pharmacists can automatically “interchange” the preferred drug for any non-preferred drug prescribed unless the practitioner indicates “dispense as written (DAW), or the prescription is for a “refill” of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drugs. In these situations the pharmacist will dispense the non-preferred drug as prescribed.

The agencies implemented TIP the week of May 1, 2004. There are approximately 5300 practitioners who have endorsed the PDL out of a total of approximately 27,000 licensed

practitioners who have prescriptive authority in the state, of which the agencies estimate 15,000 write the bulk of the prescriptions affected by this program.

Administrative Rules and the “Refill” exemption: on February 12, 2004, HCA adopted administrative rules to govern the TIP program. These are codified in WAC 182-50. While none of the specified drugs subject to the “refill” exemption are currently listed on the PDL, WAC 182-50-005 (9) defines “refill” to mean “the continuation of therapy with the same drug (including the renewal of a previous prescription or adjustments in dosage) when a prescription is for an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug. Thus, when these specific drugs come onto the PDL a patient will continue to receive these drugs when a prescription expires and must be renewed by the treating practitioner. TIP will only occur for the initiation of therapy for these drugs, although the DAW exemption to TIP for endorsing practitioners will still apply.

Drugs not listed on the PDL: drugs that are in classes that are not part of the statewide PDL remain subject to the individual agency’s prior authorization requirements, brand limits, or generic substitution under previously existing law.

Non-endorsing Practitioners: non-endorsing practitioners continue to be subject to prior authorization as applicable, even when they sign DAW on prescriptions. In addition the MAA four brand limit still applies. Practitioners have an incentive to endorse the PDL because they will see a reduction in the need for prior authorization, rewriting prescriptions and the associated administrative costs.

Endorsing Practitioner Database: to support implementation of the practitioner endorsement program, HCA used its existing pharmacy benefits management contract with ESI to develop an endorsing practitioner database that allows practitioners to sign up as an endorsing prescriber and allows pharmacists to determine the endorsing status of a practitioner. In addition, ESI coordinates with HCA on outreach, customer support, and providing statistical data to the agencies. **(See Data Exhibits 1 – 3, Appendix III. – Prescription Drug Program Background Documents and Data)**

HCA entered into an interagency agreement with the Department of Health (DOH) which allows DOH to provide information on practitioners who have prescriptive authority in Washington State. ESI uses this information to maintain the endorsing practitioner database and match practitioners by program identification number for therapeutic interchange purposes. The agencies also use this data to communicate with practitioners in the state.

Stakeholder Outreach Efforts: to publicize the endorsing practitioner program, the agencies worked with the Washington State Medical Association (WSMA), the Washington State Pharmacy Association (WSPA), the National Association of Chain Drug Stores (NACDS), the Board of Pharmacy (BOP) and other stakeholders to develop outreach information and training materials. The agencies also held various general information sessions.

During March and April 2004, agency staff worked with Washington State Pharmacy Association (WSPA) to conduct 10 training sessions around the state. Since then, the agencies have posted information and training materials on the www.rx.wa.gov website and provided ad hoc training as required.

In addition, the agencies have contracted with ePocrates as of November 2004. ePocrates is a software program for prescribers that contains drug information and formulary information for most major third-party insurers in Washington state. MAA has had its PDL information posted on ePocrates since December 2002. HCA and L&I plan to have their information posted by February 2005.

Finally, the agencies are developing a quarterly update mailing of changes to the PDL to keep practitioners aware of the drugs subject to therapeutic interchange and allow them to review their endorsing status.

The Pharmacy & Therapeutics (P&T) Committee (See Appendix IV. – Pharmacy & Therapeutics Committee)

The agencies selected the Washington Pharmacy & Therapeutics Committee (P&T Committee) members on July 15, 2003. The committee held its first meeting on September 24, 2003. The committee meets quarterly, (with additional meetings as necessary) to consider evidence-based reviews created by various Evidence-Based Practice Centers (EPCs) and make recommendations to the agencies as to what drugs to include on a state-wide preferred drug list (PDL) and subject to therapeutic interchange by the agencies.

As of January 2005, the P&T Committee has held 7 meetings and made recommendations on 12 drug classes. The committee is scheduled to meet 6 times in 2005 and review another 8 new drug classes and another 4 during 2006. By January 2007 the P&T Committee will have reviewed a total of 24 drug classes. The committee will continue to meet periodically to undertake updated reviews of existing drug classes on at least an annual basis, thereafter.

P&T Committee Administrative Rules and Plan of Operations: On February 12, 2004 the HCA adopted administrative rules to govern the P&T Committee's operations including member selection criteria, terms of service, ethics and conflict of interest standards. On December 17, 2003 the P&T Committee adopted a Plan of Operations. The Plan establishes member terms of service, governance, ethics, conflict of interest and scope of review policies. The agency directors approved the Plan on January 13, 2004

P&T Committee Selection criteria:¹⁴ because the P&T Committee also fulfills the role of the Drug Utilization Review (DUR) Board required for MAA, it must also meet federal CMS requirements applying to state Medicaid programs, in addition to the requirements established by the agencies by rule.

¹⁴ WAC 182-50-025

To meet CMS requirements, physicians and pharmacists must each represent between 31 and 51 percent of board membership. To address this requirement the agencies established a P&T Committee with 10 members that include 4 physicians, 4 pharmacists, and two ancillary healthcare providers.

CMS regulations also require that members serving on a DUR Board have recognized knowledge and expertise in one or more of the following:

- Clinically appropriate prescribing of covered outpatient drugs
- Clinically appropriate dispensing and monitoring of covered outpatient drugs
- Drug use review
- Medical quality assurance
- Disease state management

Finally, CMS regulations require that members be actively practicing in their clinical area of expertise.

Additional Criteria for State P&T Committee Selection: to address the goals of the legislation and best meet program needs, the agencies adopted the following selection criteria were added to the above federal criteria for determining P&T Committee membership:

- Candidate is not currently employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or by any agency administering state purchased health care programs
- Candidate's main practice focus is outpatient care
- Specialties represented on the Committee will include Family Practice, Internal Medicine, or Behavioral Health (due to the major role of these specialties in prescribing medications taken by program participants)
- Candidate has experience in evidence-based medicine
- Previous experience serving on a pharmacy and therapeutics committee
- Committee membership is representative of programs' geographic distribution
- Candidates who are active in professional societies are preferred
- Candidate has not had any state licensure actions or Medicaid/Medicare sanctions

P&T Committee Selection Process:

In April 2003, the agencies began to compile nominations for the P&T Committee. The request for nominations was formally announced at the Drug Utilization Education Council (DUEC) meeting in June 2003, and disseminated through the Washington State Medical Association (WSMA), Washington State Pharmacy Association (WSPA), and Washington State Academy of Physicians Assistants (WAPA). The agencies also took several nominations from groups or individuals who made inquiries.

In total, 11 physicians, 12 pharmacists, 2 physician's assistants and one ARNP were nominated. Each agency's pharmacy director and medical director reviewed the 25 nominees, based on the criteria shown above, to recommend candidates for the P&T Committee.

On July 15, 2003, the agency directors unanimously selected the final 10 members. The members will serve staggered 3-year terms. They include the targeted specialties and desired geographic distribution (four of the recommended candidates are from Eastern Washington). Collectively, they are active practitioners and represent a large number of provider training programs (such as physician residency programs) and professional associations. Four members previously served on the MAA DUEC Committee.

*P&T Committee Terms of Service/Vacancies:*¹⁵

- Members shall be appointed to a term of three years until a successor is duly appointed.
- A member may be re-appointed to one additional three year term for a total of six years. One year after the end of the six year term a person is eligible for appointment to an additional three year term.
- Committee members shall serve staggered three years terms. Of the initial appointees in order to provide for staggered terms, some members may be appointed initially for less than three years. If the initial appointment is for 24 or fewer months, that period of time shall not be counted toward the limitation of years of appointment described above.
- Vacancies on the committee will be filled for the balance of the unexpired term from nominee lists for the appropriate committee category as provided under WAC 182-50-025.

P&T Committee Officers: The P&T Committee Plan of Operations, section M. (1)-(9) provides that:

- 1) A Chair and a Vice Chair, selected by the members, shall manage the Committee and such other officers as are deemed necessary to administer the affairs of the Committee.
- 2) The term of office shall be for two years beginning on January 1st of the year following selection. Each officer shall hold office until a successor is duly elected.
- 3) The officers of the Committee shall fulfill the following functions:

¹⁵ WAC 182-50-030; Plan of Operations Section I.

a) Chair: The chair shall be the principal executive officer of the Committee and shall generally supervise and control all of the business and affairs of the Committee. The Chair will be selected in even numbered years. The Chair may appoint such other officers, subcommittees, working groups or advisory groups, as he or she deems appropriate. The Chair shall:

- i) Preside at all meetings of the Committee;
- ii) Assist with the development and implementation of a program to publicize the existence of the Committee, qualifications for appointment and procedures for maintaining public awareness of the Committee;
- iii) Complete an annual report of the activities of the Committee by May 1st of each year and forward it to the Appointing Authority; and
- iv) Shall serve as an ex-officio member of all subcommittees, working groups or advisory groups.

b) Vice Chair: The Vice Chair shall perform all duties of the Chair in the absence of the Chair or when the Chair is unable to act or refuses to act. When so acting, the Vice Chair shall have all of the powers and be subject to all of the restrictions of the Chair. The Vice Chair will be selected in odd numbered years. In addition, the Vice Chair shall:

- i) Perform such other duties as may be assigned by the chair or the Appointing Authority.
- ii) Act as the designee of the chair as ex-officio member of all Committees, working groups or advisory groups of the Committee.

4) Any officer selected or appointed by the Committee may be removed by a majority vote of the full Committee whenever in its judgment the best interests of the Committee would be served thereby.

5) The Chair and the Vice Chair should not be employed by the same entity. The Committee should strive to select officers from different regions of the state whenever possible.

6) For the 2003-4 year, the Chair shall be selected for a two-year term and the Vice Chair selected for a one-year term.

7) In the absence of both the Chair and the Vice Chair, an acting vice chair shall be appointed by a majority of the Committee present at that meeting and shall preside at that meeting of the Committee.

8) If a vacancy occurs in the office of Chair due to his or her death, resignation, removal, disqualification or other act of the Committee or the Appointing Authority, the Vice Chair shall automatically fill such vacancy until a successor is elected at the next regularly prescribed time. If a vacancy occurs in the office of Vice Chair, he or she shall be replaced by a majority vote of the members for the remainder of the term.

9) If contested, all elections of officers shall be conducted by secret ballot.

The P&T Committee Conflict of Interest Policies and Procedures: WAC 182-50-025 (8)-(11) provides that:

8) Members of the committee shall not be employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or by any state agency administering state purchased health care programs during their term shall not have been so employed and for eighteen months prior to their appointment.

(9) A member shall not have a substantial financial conflict of interest including any interest in any pharmaceutical company, including the holding of stock options or the receipt of honoraria or consultant moneys. The appointing authority in its sole discretion may disqualify any potential member if it determines that a substantial conflict of interest exists.

(10) As part of the application process, prospective committee members shall complete a conflict of interest disclosure form, provided by the appointing authority, and after appointment, annually by July 1st of each year. Members must keep their disclosure statements current and provide updated information whenever circumstances change.

(11) Committee members must agree to keep all proprietary information confidential.

The P&T Committee's Plan of Operations also contains specific conflict of interest policies and procedures as set forth in section H. (6)-(10):

6) Members of the Committee shall not be employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or by any state

agency administering state purchased health care programs during their term and for eighteen months prior to their appointment.

7) No member may have a substantial financial conflict of interest in any pharmaceutical company, including the holding of stock options or the receipt of honoraria or consultant monies. Members shall update their Conflict of Interest disclosure statements any time their circumstances change in order to ensure their information is current.

8) Any person appointed as a member of the Committee or any subcommittee, working group or advisory group established by the Committee, must disclose to the Appointing Authority any potential conflict of interest, including receipt of any remuneration, grants, or other compensation from a pharmaceutical manufacturer or pharmaceutical benefits management company prior to such appointment.

9) At each meeting any member of the Committee must recuse himself or herself from discussion and decision making of an entire drug class if he or she has a material conflict with any drug in that class. If any material conflict of interest is not disclosed by a member of the Committee on his or her application or prior to participation in consideration of an effected drug class or other action of the Committee, that person shall be subject to immediate dismissal.

10) Committee members shall not use the name of the Committee in any publication, meeting, negotiation, or promotion without prior approval of the Appointing Authority.

P&T Committee Evidence-Based Review Standards: The Washington P&T Committee's review process is set forth in its Plan of Operations; section G. (1)-(7):

The P&T Committee will evaluate evidence-based reviews of classes of prescription drugs provided by OHSU EPC or other contracted entity. The evidence-based reviews shall be based on well designed, well-conducted studies that:

- 1) Consider the overall quality of the evidence available at the time of review, including a consideration of whether the study compares the safety, efficacy or effectiveness of similar drugs, rather than just compared to placebo;
- 2) Select and refine questions that assist the Committee in evaluating provider and patient perspectives;
- 3) Make use of an independent, systematic review of evidence of the relative safety, efficacy, and effectiveness of prescription drugs in a class;

- 4) Produce explicit, defensible recommendations based on careful evaluation of the available evidence at the time of the review;
- 5) Evaluate each class of drugs in a manner free of bias emphasizing the best evidence as reported by OHSU or other entity;
- 6) Review direct evidence, if available at the time of review, that addresses health outcomes rather than intermediate outcomes, including the spectrum of patients to whom a drug will be prescribed (not just highly selected patients in research studies); and
- 7) Consider the potential harms as well as the benefits of the intervention being considered.

The P&T Committee may consider such other evidence and reviews as the Committee deems appropriate to a well-informed review.

The Evidence-Based Review Process (See Summary Overview, Appendix III. – Prescription Drug Program Background Documents and Data): The agencies participate in the Drug Effectiveness Review Project (Project) to provide evidence-based reports prepared by various Evidence-Based Policy Centers (EPCs) for the P&T Committee to review. This Project is coordinated by the Center for Evidence-Based Policy at Oregon Health & Sciences University (OHSU). The Project is a collaboration of twelve states and two non-profit organizations to obtain the best available evidence on effectiveness and safety comparisons between drugs in the same therapeutic classes.

The Role of the OHSU Center for Evidence-Based Policy: The Center for Evidence-Based Policy supports the collaboration by executing the agreements and contracts required to operate the collaboration, and by staffing the governance process that directs the Project. In addition, the Center supports communication between the participating organizations and the EPCs, provides technical assistance to participating organizations, ensures that timelines are met, and manages communication among the participating organizations, and between pharmaceutical companies and the Project. The Center for Evidence-Based Policy does not participate in the evaluation of the evidence.

The Role of the Evidence-Based Practice Centers (EPC): The Project relies on a series of comprehensive, updated and unbiased systematic reviews conducted by the various EPCs, which are designated and funded by the Department of Health and Human Services, Agency for Healthcare Research and Quality.

The EPCs perform systematic reviews of medical evidence comparing the safety, efficacy, and effectiveness of these drug classes and updates these reviews at least every twelve months. As a part of the review process, the EPC consults with health care specialists and other stakeholders to provide feedback to ensure that the concerns of patients and practitioners are thoroughly considered, and develops key questions to guide the systematic reviews. The key questions specify the clinical conditions (diagnoses,

disease) of interest for the particular review; define the populations, interventions, and outcomes (expected benefits, potential risks or harms) of interest for the systematic review; and distinguish intermediate outcomes (e.g. laboratory test results or biometric measures) from true health outcomes (e.g. death, morbidity, functioning, quality of life) and focus the research on true health outcomes when possible.

The Role of the Oregon EPC is to provide support to the agencies and the P&T Committee as it reviews the evidence presented. The reports created by the Oregon EPC only consider the available scientific evidence without regard to drug cost information.

The Role of the Washington State P&T Committee: All P&T Committee meetings are open to the public and notice is published in the Washington State Register and sent to interested parties as required by state open public meetings law. The P&T Committee also notifies interested parties of its intent to consider a particular class of drugs for inclusion on the state's preferred drug list 30 days prior to meeting.

At each meeting the P&T Committee reviews the report created by the EPC on a particular drug class with assistance from EPC staff and considers stakeholder comments. The P&T Committee then evaluates the evidence of similar safety, efficacy, and effectiveness for the drugs in a class and makes a recommendation to the agencies as to which drugs (if any) in a given class are essentially the same in terms of safety and efficacy and thus can be subject to therapeutic interchange.

The P&T Committee has developed a schedule for evaluation of both the drug class reviews and annual updates developed by the EPC. See more at: www.rx.wa.gov

The Role of the State Agencies: The next step is for the agencies to review the P&T Committee's recommendations as to which drugs (if any) in a class can be safely interchanged and to perform a cost analysis of those drugs to determine which drug, or drugs should be on the PDL. The agencies' cost analysis process is set forth in **Appendix III. – Prescription Drug Program Background Documents and Data**, along with an example of the resulting recommendation summary that is produced for each drug class.